K122218
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510(k) Summary of Safety and Effectiveness

MAR 2 1 2013

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this information serves as a Summary of Safety and Effectiveness for the use of the ADVANCE® Total Knee System.

Submitted By:	Wright Medical Technology, Inc. 5677 Airline Rd, Arlington TN, 38002 (800) 238-7188
Date:	February 19, 2013
Contact Person:	Danielle Mueller *Project Manager*
Proprietary Name:	ADVANCE® Total Knee System
Common Name:	Patella
Classification Name and Reference:	21 CFR 888.3560 Knee joint Patellofemorotibial Polymer / Metal / Polymer Semi-Constrained Cemented Prosthesis Class II 21 CFR 888.3565 Knee joint Patellofemorotibial Metal / Polymer Porous-Coated Uncemented Prosthesis Class II
Subject Product Code and Panel Code:	Orthopedics/87/JWH, MBH
Predicate Devices:	ADVANCE® Total Knee System AXIOM® Total Knee System 510(k)s: K953439, K061223, K894334

DEVICE INFORMATION

A. Intended Use

The ADVANCE® Total Knee System is indicated for use in knee arthroplasty in skeletally mature patients with the following conditions:

1. Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
2. Inflammatory degenerative joint disease including rheumatoid arthritis;
3. Correction of functional deformity;
4. Revision procedures where other treatments or devices have failed; and treatment of fractures that are unmanageable using other techniques.

Porous-coated total knee replacement components are for use without bone cement.

B. Device Description

The purpose of this submission is to add patellar components to the ADVANCE® Total Knee System. The design features of the subject patellae are summarized below:

- All-poly patellae manufactured from UHMWPE
  - Available in sizes 25-41, single- or tri-peg design

- Metal-backed patellae manufactured from UHMWPE and CoCr alloy
  - Available in sizes 29-38, tri-peg design with porous coating

The ADVANCE® patellar components were evaluated via mechanical testing and engineering analyses; including static stability, contact area, and interface strength. In addition, the porous coating for the metal-backed design was fully characterized as well as tested in static shear. A review of these results indicates that the subject devices are equivalent to predicate devices and are capable of withstanding expected *in vivo* loading without failure.

C. Substantial Equivalence Information

The indications for use of the ADVANCE® Total Knee System are unchanged as a result of the addition of the subject patellar components. The design features and materials of the subject devices are identical to those of the predicate devices. The fundamental scientific technology of the modified devices has not changed relative to the predicate devices. The safety and effectiveness of the patellae of the ADVANCE® Total Knee System are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 21, 2013

Wright Medical Technology, Incorporated
% Ms. Danielle Mueller
Project Manager
5677 Airline Road
Arlington, Tennessee 38002

Re: K122218
Trade/Device Name: ADVANCE® Total Knee System
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class: II
Product Codes: MBH, JWH
Dated: February 19, 2013
Received: February 20, 2013

Dear Ms. Mueller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122218

Device Name: ADVANCE® Total Knee System

Indications For Use:

The ADVANCE® Total Knee System is indicated for use in knee arthroplasty in skeletally mature patients with the following conditions:

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Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.
Division of Orthopaedic Devices